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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

HM12/0512

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ART UNIT	PAPER NUMBER
WORRALL, T	
1642	8

DATE MAILED: 05/12/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on April 14, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.
Of the above, claim(s) 7-10 and 13 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-6, 11-12, and 14-15 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40517

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-6, 11-12, and 15 in Paper No. 7 is acknowledged.

2. CLAIMS 1-15 ARE PENDING.

CLAIMS 7-10, 13, and ~~14~~ 15 HAVE BEEN WITHDRAWN FROM CONSIDERATION, AS BEING DRAWN TO NON-ELECTED INVENTIONS.

CLAIMS 1-6, 11-12, and 15 ARE EXAMINED ON THE MERITS.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-6, 11-12, and 15 of this application. The claims are drawn to compositions comprising SEQ ID NOS: 1-7. Different sequence are disclosed as SEQ ID NO:1-7 in provisional application 60/048,810. Claims to SEQ ID NOS: 1-7 of the instant application are therefore not supported by provisional application 60/048,810, and the priority date of the instant application is the June 5, 1998 filing date.

Drawings

4. The drawings are objected to. Please see the attached Notice of Draftperson's Patent Drawing Review. Correction is required. Applicant is required to submit a proposed drawing

correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 12, 14, and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as broadly written, embrace the naturally occurring polypeptide product as found in nature. Therefore, the claims must be limited so that they do not encompass naturally occurring products as found in nature. It appears that applicant does not intend to claim the naturally occurring product. Amending the claims to recite the purified composition would obviate this rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 11, 12, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 5, 12, and 15 specifically recites a nucleotide sequence that has "50% identity" with the claimed invention.

The term "__% identity" (e.g. "50% identity") in claims (and dependent claims thereof) is a relative term which renders the claims indefinite. The term "% identity" in the specification does not provide a standard for ascertaining the requisite degree of sequence similarity, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

A general definition of "% identity" was found on page 13, lines 8-18 of the specification. The specification further refers to a number of program algorithms that may be used to measure sequence identity. However, this method may use different parameters in determining the "% identity," which could result in a different assessment of the "% identity" of a sequence. Absent *both* the specific algorithm *and* the parameters employed to determine percent identity of two nucleic acid sequences, the metes and bounds of the nucleic acids as instantly claimed can not be ascertained.

Removing the limitation "% identity" would obviate this rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (GenBank Accession T94049). The claims are drawn to a purified polynucleotide that is capable of hybridizing to the nucleic acid of a LS147 gene and has at least 50% sequence identity

to a sequence selected from the group consisting of SEQ ID NO:4 or 7. Claims 2 and 3 are further drawn to purified polynucleotides produced by recombinant or synthetic techniques, respectively. Claim 4 further limits claim 1 wherein the claimed sequence encodes at least one LS147 epitope.

Hillier et al teach a polynucleotide sequence that includes the claimed sequences that hybridize and have at least 50% identity to SEQ ID NO:4 and 7. The full length sequences taught by Hillier et al would hybridize under low stringency conditions to SEQ ID NO:4 and 7.

Claims 2 and 3 are drawn to a polynucleotide produced by recombinant or synthetic techniques. The method in which the polynucleotides were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. Therefore, claims 2 and 3 are also rejected over Hillier et al under 35 USC 102(b).

Claim 4 is further drawn to polynucleotides that encode at least one LS147 epitope. An epitope was generally and well known to one of ordinary skill in the art as an amino acid sequence of a protein, usually 5-6 amino acids in length, that provokes an immune response.

Considering the substantial sequence identity of Hillier et a (A) to SEQ ID NO:4 and 7, there is at least one LS147 epitope encoded by the sequence taught by Hillier et al.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by the NEB 1994/1995 Catalog. The claims are drawn to a fragment of SEQ ID NO:4.

The NEB catalog teaches a SmaI hexamer that hybridizes to bases 57-62 of SEQ ID NO:4 under high stringency conditions (page 95). Claims 2 and 3 are rejected, since the method in which the polynucleotides were produced is immaterial to their patentability, as discussed supra.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 5, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (GenBank Accession T94049) in view of Ausubel et al. The claims are drawn to a recombinant expression system containing a fragment of SEQ ID NO:4 or 7 and a cell transfected with the recombinant expression system.

Hillier et al are discussed supra. The reference differs from the instant invention by not teaching that the polynucleotide sequence can be included in a recombinant expression system and introduced into a cell.

Ausubel et al teach a general and well known method to introduced sequences into an expression vector and transfect cells with the expression vector.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the sequence taught by Hillier et al into the expression system taught by Ausubel et al. One of ordinary skill in the art at the time the invention was made would have been motivated to combine the sequence of Hillier et al with the expression method and cell transfection method taught by Ausubel et al since it was well known in the art that polynucleotide sequences can be routinely expressed using recombinant expression systems. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. NO CLAIM IS ALLOWED.

14. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 U.S.C.122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy A. Worrall, Ph.D.

April 26, 1999

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER